REMARKS

Claims 1-29 have been cancelled without prejudice. Claims 30-41 are pending. No new matter is introduced by new claims 39-41. Support for these claims can be found in the Figures, particularly, Figures 3, 4, and 5. Additional support can be found in the specification at page 2, lines 12-30.

New Matter Rejections.

Claims 21-29 were rejected as not being properly supported by the original specification. While applicants do not agree with the Examiner's arguments, these claims have been cancelled without prejudice in the interest of expediting prosecution, thereby rendering this rejection moot.

Claim Rejections under 35 U.S.C. §112 ¶ 2.

Claims 21-29 were rejected as allegedly being indefinite. While applicants do not agree with the Examiner's arguments, these claims have been cancelled without prejudice in the interest of expediting prosecution, thereby rendering this rejection moot.

Claim Rejections under 35 U.S.C. §112 ¶1 .

Claims 21-38 were rejected for allegedly lacking sufficient disclosure in the specification to have enabled one of ordinary skill in the art to practice the invention. While applicants do not agree with the Examiner's arguments, claims 21-29 have been cancelled without prejudice in the interest of expediting prosecution, thereby rendering this rejection moot as to these claims.

With respect to claims 30-38 applicants respectfully traverse the rejection and submit that the Examiner is clearly wrong in rejecting the claims for alleged lack of enablement. Claim 30 is directed to nine individual, clearly defined oligopeptides. A simple disclosure of these materials in the specification with some indication of their utility is all that is needed for enablement of such a claim.

In addition, fusion proteins and methods of preparing them are well known in the art. One of ordinary skill in the art would have recognized, from the disclosure of the present invention, that fusion of the oligopeptides of claim 30 to a polypeptide, as set forth in claim 31 (e.g., to the polypeptides specified in claims 32-38) will enhance transport of the polypeptide into cells. The oligopeptides of claim 30 are described with clear specificity, and the classes of polypeptide fusion partners set forth in claims 32-38 are well known materials, most of which

have been known for many decades. The claims merely call for covalently binding a specified oligopeptide to a specified polypeptide. Hence, one of ordinary skill in the biotechnological art would have been able to practice the invention of claims 31-38 at the time the invention was made without undue experimentation. Accordingly, claims 31-38 are also supported by an enabling disclosure. The rejection should be withdrawn.

Claims 21-29 and 31-38 were rejected as allegedly lacking a proper written description in the original specification. While applicants do not agree with the Examiner's arguments, claims 21-29 have been cancelled without prejudice in the interest of expediting prosecution, thereby rendering this rejection moot as to these claims. As to claims 31-38, applicants respectfully traverse the rejection. The Examiner's position is that the term "fusion protein" and the various classes of compounds being claimed as part of the fusion protein, are not sufficiently defined in the specification. Applicants submit that these terms are well known in the art and that one of ordinary skill at the time the invention was made would have understood their meaning with sufficient specificity that they would have recognized that applicants had possession of the claimed invention. The term "fusion protein" is well understood in the art to mean an *non-natural* protein comprised of at least two different protein segments covalently bound together, as described in the specification at pages 4 and 5. As noted above, the oligopeptides are set forth clearly and exactly in claim 30. In addition, the various classes of polypeptide fusion partners set forth in claims 32-38 are very well known materials, and are thus described with enough specificity for one of ordinary skill in the biotechnological art to have envisioned the scope of these polypeptides. Claims 31-38 merely require covalently binding a specific oligopeptide with the polypeptide. Accordingly, one of ordinary skill in the art would have recognized that Applicants had possession of the claimed invention at the time the application was filed, particularly with respect to claims 32-38. The rejection should be withdrawn.

Rejections based on 35 USC §102 - anticipation/lack of novelty.

Claims 22, 23, 27, 31, 32, and 36 were rejected as allegedly lacking novelty in view of Dr. Hildt's 1995 *Oncogene* article. Applicants traverse this rejection. While applicants do not agree with the basis of the rejection, the rejection is rendered moot as to claims 22, 23, and 27, which have been cancelled without prejudice. As to claims 31, 32, and 36, these claims are not product

by process claims. As noted above, the term "fusion protein" is well understood in the art to mean an *non-natural* protein comprised of at least two different protein segments covalently bound together, as is pointed out in the specification at pages 4 and 5 of the specification. One of ordinary skill in the art would have understood the fusion proteins of claim 31, 32, and 36 to be separate and distinct from the protein described in the article, especially since the specification points out that the fusion proteins are not natural HBV proteins. In addition, this distinction is particularly clear in claims 32, and 36, which recite specific classes of polypeptides that are covalently linked to the oligopeptide, and are clearly not directed to a natural HBV protein. Accordingly, the HBV protein disclosed in the applied article does not anticipate claims 31, 32, or 36.

Claims 21-23 and 27 were rejected as allegedly being anticipated by Van Nieuwstedt, *et al.* (WO98/50426). Applicants respectfully submit that the basis for the Examiner's rejection that the peptide SIQTAFNQGAGT falls within the scope of claim 21 is clearly incorrect. The amino acid residue at position 9 in this peptide is glycine (G). Glycine has a negative hydropathy value, not a positive value as implied by the Examiner. Nevertheless, in the interest of expediting prosecution, this rejection is moot in that claims 21, 23 and 27 have been cancelled without prejudice.

Claim 21 was rejected as being anticipated by the Evotec Biosystems patent (DE 19808258). Without conceding novelty, this rejection is rendered moot in that claim 21 has been cancelled without prejudice.

Claims 21-23, 27, 30-32, and 36 were rejected as allegedly being anticipated by NCBI Accession No. 540642 (protein). Applicants traverse this rejection. Without conceding novelty this rejection is rendered moot as to claims 21-23, and 27 by the cancellation of claims 21-23, and 27 without prejudice. Applicants respectfully submit that the Examiner is clearly wrong with respect to claims 30-32, and 36. With respect to claim 30, the NCBI Accession No. 540642 sequence cited against the claim is much larger than the isolated 12-amino acid oligopeptides that are claimed. Thus, the applied reference *cannot* anticipate claim 30.

Furthermore, with respect to claims 31, 32, and 36, Applicants submit that the cited sequence is not a fusion protein, as defined in the specification, and thus likewise cannot

anticipate these claims.

Claims 21-23, 27, 30-32, and 36 were rejected as being anticipated by NCBI Accession No. 138800 (protein). Applicants traverse this rejection. Without conceding novelty this rejection is rendered moot as to claims 21-23, and 27 by the cancellation of claims 21-23, and 27 without prejudice. Applicants respectfully submit that the Examiner is clearly wrong with respect to claims 30-32, and 36. With respect to claim 30, the NCBI Accession No. 540642 sequence cited against the claim is much larger than the isolated 12-amino acid oligopeptides that are claimed. As such, the applied reference *cannot* anticipate claim 30.

Furthermore, with respect to claims 31, 32, and 36, Applicants submit that the cited sequence is not a fusion protein, as defined in the specification, and thus likewise cannot anticipate these claims.

All the rejections of claims 30-32 , and 36 under 35 USC §102 should be withdrawn.

Rejections based on 35 USC §103(a).

Claims 21 and 30 were rejected as allegedly being obvious over the teachings of Dr. Hildt's 1995 *Oncogene* article, particularly the disclosure in this article of the significance of SEQ ID NO: 2. This rejection is moot as to claim 21 which has been cancelled without prejudice and without conceding obviousness. Applicants traverse the rejection of claim 30, which is directed to specific 12-amino acid oligopeptides. The 12-amino acid *region* discussed in the article does not render claim 30 obvious because the function of this region (dimerization and transcriptional activation), reported in the reference, would not have led one to *isolate* this particular peptide, since dimerization and transcriptional activation would be functions specific to the full length protein. Thus, one of ordinary skill in the art would not have been motivated to isolate a 12-amino acid oligopeptide of the specified sequence. Accordingly, the rejection of claim 30 under 35 USC §103 should be withdrawn.

Three new independent claims 39-41 have been added. These claims are directed to three specific subsets of the oligonucleotides set forth in claim 30. None of these specific oligopeptides is taught or suggested by the applied prior art. Accordingly, Applicants believe that claims 39-41 are certainly allowable.

Conclusion.

Applicants submit that the present pending claims 30-41 fall within the scope of the invention searched, i.e., original claim 1, and are patentable under 35 U.S.C. 112 and over the applied art. Applicants respectfully request reconsideration and early allowance of all claims.

Respectfully submitted,

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